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ORIGINAL ARTICLE

Comparative Study Between Laparoscopic Varicocelectomy and Foam Injection Sclerotherapy by Using Interventional Catheterization in the Treatment of Primary Varicocele

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Abstract

Background: The incidence of varicocele in the general population ranges from 15 to 20%, and 30 to 40% in infertile men. Varicocele is dilated tortuous veins of the pampiniform plexus the venous sinuses that drain the testicles. These sinuses primarily drain into the internal spermatic vein (gonadal vein).

Aim and objectives: To compare laparoscopic varicocelectomy versus foam injection sclerotherapy of a polidocanol in a concentration of 3% solution, by using interventional catheterization in the treatment of primary varicocele.

Patients and methods: This prospective randomized study was conducted on 50 patients with primary varicocele. It was conducted in the Department of Vascular Surgery, Al Azhar University Hospitals, Cairo (Al-Hussein and and said-Galal University Hospitals). Patients were divided into two groups.

Results: Statistically insignificant difference between patients with injection sclerotherapy and patients with laparoscopic varicocelectomy regarding their Computer-Assisted Sperm Analysis (P > 0.05). lower Wound infection, Hematoma Orchitis, Scrotal edema, Hydrocele, Scrotal emphysema, and higher Testicular pain in injection sclerotherapy than patients with laparoscopic varicocelectomy however, this difference was statistically insignificant except for hematoma (P < 0.05).

Conclusion: We can conclude that injection sclerotherapy may be a preferable treatment option for patients with unilateral varicocele. Further studies with large scales are needed to confirm our results.

Keywords: Foam injection sclerotherapy, Interventional catheterization, Laparoscopic varicocelectomy

1. Introduction

The incidence of varicocele in the general population ranges from 15 to 20%, and 30 to 40% in infertile men. Varicocele is dilated tortuous veins of the pampiniform plexus, the venous sinuses that drain the testicles. These sinuses primarily drain into the internal spermatic vein (gonadal vein).¹

The right internal spermatic vein normally drains obliquely into the anterolateral inferior vena cava (IVC), just inferior to the right renal vein, whereas the left spermatic vein normally drains perpendicularly into the left renal vein. The perpendicular

termination exposes the left spermatic vein to compromised flow in the setting of increased left renal venous pressures. This flow abnormality is augmented when there is compression of the left renal vein between the aorta and superior mesenteric vein ('nutcracker syndrome'). Additionally, the increased length of the left-sided vein when compared with the right contributes to the increased prevalence of left-sided varicocele. This difference in incidence is such that an isolated right varicocele is rare, and some investigators advocate prompt evaluation for a retroperitoneal mass. Another factor that predisposes to formation of a left-sided

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varicocele is compression of the left spermatic vein by the left colon. 1

This prevalence increases with age, approaching 42% in the elderly population. Due to certain anatomic causes, left-sided varicocele is 10 times more common than the right-sided varicocele. While bilateral varicocele occurs in less than 10% of patients and isolated to the right occurs in less than 1%.²

Celsus provided a detailed description of varicocele and its operative treatment in the first century and, since that time, a wide range of conservative therapies have been recommended including suspension, compression, cold scrotal showers, astringents, and moderation of sexual activity. Perhaps more interesting is the early evolution of surgical treatments, which involved a *trans*-scrotal approach and included cauterization, clamps, subcutaneous hoops, partial excision of the scrotum, ligation, and resection of the dilated venous plexus, and even semi-castration. More recently, laparoscopic approaches have been developed and imaging has improved dramatically as percutaneous embolization.³

Orchalgia is present in ~2–10% of men with varicocele, and is described as dull, throbbing pain exacerbated by straining and prolonged standing. This pain classically extends from the scrotum to the ipsilateral inguinal region following the path of the spermatic cord. Varicocele has been identified as the cause of chronic scrotal pain in 2–14% of men.⁴

During venography, perforation of the internal spermatic vein and dissection of the IVC/renal vein may occur, reported in up to 4.6 and 4.1% of cases, respectively. This complication is usually without clinical consequence. Though rare, more serious complications from varicocele embolization have been described, including coil migration to the right atrium and pulmonary arteries, as well as bowel necrosis following sclerotherapy.⁵

This work aimed to compare laparoscopic varicocelectomy versus foam injection sclerotherapy of a polidocanol in a concentration of 3% solution, by using interventional catheterization in the treatment of primary varicocele as regard to advantages, disadvantages, efficiency, complications as well as recurrence rate to choose the best treatment method.

2. Patients and methods

It was conducted in the department of vascular surgery, Al-Azhar University Hospitals, Cairo (Al-Hussein and and said-Galal University Hospitals).

This prospective randomized study was conducted on 50 patients with primary varicocele.

Inclusion criteria: age from 16 to 50 years old, patients were sufficiently mentally healthy to

consent to the procedure, significant testicular asymmetry (>20%) demonstrated on serial examinations, testicular pain, abnormal semen analysis results, palpable varicocele on physical examination. The couple has known infertility, the female partner has normal fertility or a potentially treatable cause of infertility, and time to conception is not a concern and progressive testicular atrophy.

Exclusion criteria: inflammation skin disorder in access puncture area, obstructive azoospermia, Genetic abnormalities, above 50 years of age, below 16 years of age, patients with subclinical varicocele, patients with normal semen analysis and idiopathic nonobstructive azoospermia.

2.1. Methods

Data was collected and maintained regarding to: age, unilateral or bilateral varicocele.

All patients were subjected to complete history taking (personal history, complaint and its duration, present history, history of sensitivity to drugs, medical history and past surgical history), physical examinations (general examination and BMI), investigational studies (routine laboratory investigations (semen analysis), radiological investigation (duplex ultrasound for the varicocele).

Varicocele physical examination: upon palpation of the scrotum, a nontender, twisted mass along the spermatic cord was felt (it feels like a bag of worms.) The mass may not be obvious, especially when lying down. The testicle on the side of the varicocele may or may not be smaller compared with the other side (visual inspection, palpation, grading and differential diagnosis) Figs. 1–3.

2.2. The procedure

Patients were divided into two groups:

Group A: 25 patients of this group performed by Laparoscopic closure of varicocele, through the following steps:

Anesthesia: The procedure was typically performed under general anesthesia with strict sterile conditions. The patient was positioned in the supine low lithotomy position then given general anesthesia in preparation for the laparoscopic surgery that was performed using a three-port technique. A Veress needle was inserted through the umbilical cord and inflated with carbon dioxide gas. To generate a carbon dioxide pneumo-peritoneum at a pressure of 14 mmHg.

Before injecting CO_2 through the veress needle, we entered a 20 ml needle syringe containing saline to ensure that the needle was in the intraperitoneum.

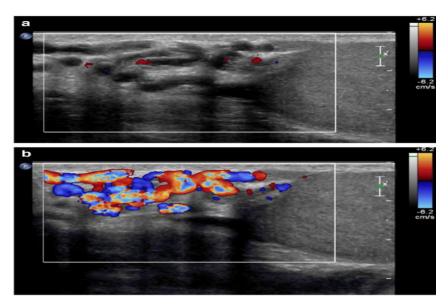
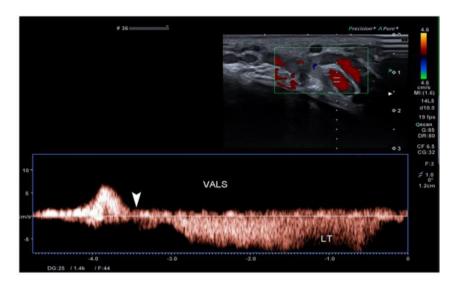


Fig. 1. Small varicocele lying above the testis (Sarteschi grade II). Colour doppler images obtained at rest (a) and during valsalva (b) showing that reflux was detected only during Valsalva.



 $Fig.\ 2.\ Spectral\ Doppler\ analysis\ during\ valsalva.\ Flow\ reversal\ demonstrated\ on\ the\ implementation\ of\ valsalva\ (arrowhead)\ and\ persisting\ for\ more\ than\ 2\ s.$

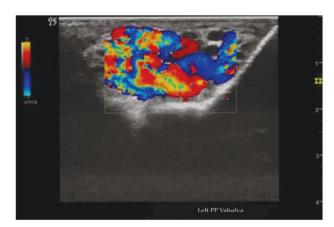


Fig. 3. Color Doppler ultrasound of the scrotum showing dilated left pampiniform venous plexus with augmentation after valsalva maneuver.

Once the saline was freely flowing and no blood or fecal contents were being removed, the needle can be removed as well as laparoscopic varicocelectomy can be performed on the belly. We planned to use a transverse midline initial incision to insert a 5 mm trocar. To see the abdominal cavity and pelvis, a telescope was inserted sub umbilically as well as a video camera was hooked onto the eyepiece. The patient was then positioned in a variation of the Trendelenburg position. The patient lied on their side while two 5 ml trocars were inserted halfway between the umbilicus and the anterior superior iliac spine. Each side's vascular bundle of testicles was located.

We started with the correct bundle. The vas deferens was located when it emerged medially from

the internal ring and runs into the pelvis, and the vascular bundle was followed vertically down to its insertion into the ring. Before moving on, these points of reference were always checked off. After making a 1 cm transverse incision over the bundle, the parietal peritoneum was raised as well as the connective tissue connecting the vessels was teased apart.

First, the testicular artery was located by its pulse, which was noticeable in varied degrees. The veins in the testicles were uncovered, clipped in two locations using tiny titanium clips, as well as snipped in the middle to eliminate the possibility of recanalization. The procedure on the left side was the same as that for the right. The abdominal incisions were sutured once the CO₂ had been entirely removed from the abdomen.

Group B: 25 patients of this group performed by foam injection sclerotherapy by interventional catheterization through the following steps:

Anesthesia: the procedure was performed under to local anesthesia and strict sterile conditions.

Vascular access: right internal jugular vein or right common femoral vein was used for the left-sided varicocele. Getting a catheter into the left renal as well as internal spermatic veins was more difficult from the left side, hence right-sided access was typically favored. The internal jugular vein or basilic vein was used for the right-sided varicocele. Below the right renal vein, on the right anterolateral IVC, at an acute angle, was usually where you found the

right internal spermatic vein. A six-French vascular sheath was used to get access.

Venography: A 4–5 French diagnostic catheter guided with 0.035 inch hydrophilic wire should be used to perform selective venography of the renal vein and the gonadal vein orifice. To selectively catheterize the internal spermatic vein prior to embolization, the catheter tip should be positioned at the junction of the distal internal spermatic vein as well as the pampiniform plexus under fluoroscopic guidance.

Follow-up of patients: patients were followed up immediately at the first postprocedure day then at one week, 1, 3, and after 6 months as regard to efficacy of the procedure as well as complications. Follow-up by Doppler ultrasound should be performed at 3 months and semen analysis at 4–6 months in patients undergoing therapy due to infertility.

Ethical Consideration: written consent was taken from all patients before including them in the study, aims of the study and any possible risk was discussed with all patients, privacy of the collected data was assured, investigations were delivered to patients and follow-up of the patients was done after the procedure.

2.3. Sample size

We used to calculate the sample size by considering the following assumptions: -95% two-sided confidence level, with a power of 80%, and α error of 5%. The final maximum sample size taken from output

Sample Size For Comparing Two Means

Input Data							
Confidence Interval (2-sid		5%					
Power 80% Ratio of sample size (Group 2/Group 1) 1							
	Group 1	Group 21) oifference*				
Mean	23.8	29.8	-6				
Standard deviation	6.1	8.2					
Variance	37.21	67.24					
Sample size of Group 1		23					
~	4	23					
Sample size of Group 2							

^{*}Difference between the means

Results from OpenEpi, Version 3, open source calculator--SSMean Print from the browser with ctrl-P or select text to copy and paste to other programs.

was 46. Thus, the sample size was increased to 50 patients to assume any drop out cases during follow-up.

2.4. Statistical analysis

Data were checked, entered and analyzed using SPSS (New York City, USA) for data processing. The following statistical methods were used for analysis of results of the present study. Data were expressed as number and percentage for qualitative variables and mean + SD for quantitative one.

The comparison was done using: the student 't' test, Mann–Whitney test, χ^2 , Z-test for percentage and odds ratio (OR).

3. Results

Table 1.

This table showed a statistically insignificant difference between patients with injection

sclerotherapy and patients with laparoscopic varicocelelctomy regarding age, BMI, smoking, testicular asymmetry, varicocele grade, and infertility duration (P > 0.05) Table 2.

This table showed a statistically insignificant difference between patients with injection sclero-therapy and patients with laparoscopic varicocelectomy regarding their vital data (P > 0.05) Table 3.

This table showed a statistically insignificant difference between patients with injection sclerotherapy and patients with laparoscopic varicocelelctomy regarding their computer-assisted sperm analysis (P > 0.05) Table 4.

This table showed a statistically significant lower recovery time, earlier resume excursive and earlier resume sexual activity after procedure in patients with injection sclerotherapy than patients with laparoscopic varicocelelctomy (P < 0.05). However,

Table 1. Comparison of age and BMI among the study groups.

	Laparoscopic varicocelelctomy $(N = 25)$		Injection sclerotherapy ${(N=25)}$		Test of significance	
	Mean	SD	Mean	SD	z/χ^2	P value
Age (years)	39.48	1.90	39.12	3.32	0.471	0.640
BMI	24.44	3.65	24.93	2.85	-0.531	0.598
Infertility duration	7.92	2.20	6.52	2.92	1.917	0.062
Testicular asymmetry %	45.40	6.18	42.88	10.22	1.055	0.297
Smoking	N (%)		N (%)			
No	8 (32)		12 (48)		1.333	0.248
Yes	17 (68)		13 (52)			
Infertility						
1–3 years	1 (4)		5 (20)			
4–6 years	6 (24)		7 (28)			
7–10 years	11 (44)		10 (40)		4.391	0.222
11–15 years	7 (28)		3 (12)			
Varicocele grade	N (%)		N (%)			
G II	10 (40)		12 (48)		0.325	0.569
G III	15 (60)		13 (52)			

SD, standard deviation; t, independent student t-test.

P value greater than 0.05: nonsignificant; P value less than 0.05: significant; P value less than 0.001: highly significant.

Table 2. Comparison of vital data among the study groups.

	Laparoscopic varicocelelctomy $(N = 25)$		Injection scler	rotherapy	Test of significance	
			(N=25)			
	Mean	SD	Mean	SD	t	P value
HR	79.00	5.40	78.00	4.79	0.693	0.492
RR	17.16	0.62	17.20	0.65	-0.223	0.825
Temp	37.02	0.15	37.04	0.14	-0.387	0.700
SBP	111.40	9.74	113.40	6.88	-0.839	0.406
DBP	71.20	5.26	72.00	4.08	-0.601	0.551

SD, standard deviation; t: independent student t-test; SBP, systolic blood pressure, DBP, diastolic blood pressure; HR, heart rate; RR, respiratoty rate.

P value greater than 0.05: non significant; P value less than 0.05: significant; P value less than 0.001: highly significant.

Table 3. Comparison of computer-assisted sperm analysis among the studied groups.

	Laparoscopic varicocelelctomy $(N = 25)$		Injection sclerotherapy $(N = 25)$		Test of significance	
	Mean	SD	Mean	SD	t/z	P value
VSL (μm/s) straight-line velocity	49.08	8.34	53.76	11.52	-1.646	0.106
VCL (im/s) curvilinear velocity	76.04	22.40	86.80	33.15	-1.345	0.185
LIN (%) linearity	57.56	4.30	59.28	5.05	-1.297	0.201
Total sex chromosome disomy	1.55	0.24	1.53	0.40	0.229	0.820
Total chromosome disomy	1.16	0.36	0.89	0.72	1.727	0.091

SD, standard deviation; t, independent student t-test; z, Mann–Whitney U test.

P value greater than 0.05: nonsignificant; P value less than 0.05: significant; P value less than 0.001: highly significant.

Table 4. Comparison of operation data among the studied groups.

	Laparoscopic varicocelelctomy $(N = 25)$		Injection sclerotherapy $(N = 25)$		Test of significance	
	Mean	SD	Mean	SD	t	P value
Operation duration (min)	30.80	4.40	31.00	3.86	-0.171	0.865
Recovery time (days)	13.76	1.81	2.20	0.65	30.089	0.0001
Resume excursive (days)	10.96	1.84	9.60	1.94	2.548	0.014
Resume sexual activity (weeks)	3.64	0.49	2.24	0.44	10.675	0.0001

SD, standard deviation; t, independent student t-test.

P value greater than 0.05: non significant; P value less than 0.05: significant; P value less than 0.001: highly significant.

Table 5. Comparison of postoperative outcome among the study groups.

	Injection sclerotherapy	Laparoscopic varicocelelctomy	Test of significance	
	$\overline{\left(N=25\right)N\left(\% ight)}$	(N = 25) N (%)	χ^2	P value
Wound infection				
No	23 (92)	18 (72)	3.388	0.066
Yes	2 (8)	7 (28)		
Hematoma	N (%)	N (%)		
No	25 (100)	20 (80)	5.556	0.018
Yes	0	5 (20)		
Orchitis	N (%)	N (%)		
No	25 (100)	24 (96)	1.020	0.312
Yes	0	1 (4)		
Scrotal edema	N (%)	N (%)		
No	24 (96)	22 (88)	1.087	0.297
Yes	1 (4)	3 (12)		
Hydrocele	N (%)	N (%)		
No	24 (96)	23 (92)	0.355	0.552
Yes	1 (4)	2 (8)		
Scrotal emphysema	N (%)	N (%)		
No	25 (100)	24 (96)	1.020	0.312
Yes	0	1 (4)		
Testicular pain	N (%)	N (%)		
No	18 (72)	23 (92)	3.388	0.066
Yes	7 (28)	2 (8)		

χ2: Chi- Square test.

P value greater than 0.05: nonsignificant; P value less than 0.05: significant; P value less than 0.001: highly significant.

there is insignificant difference between the two groups as regard the duration of procedure (P > 0.05) Table 5.

This table showed a lower Wound infection, Hematoma Orchitis, Scrotal edema, Hydrocele, Scrotal emphysema and higher Testicular pain in injection sclerotherapy than patients with laparoscopic varicocelelctomy, however, this difference was statistically insignificant except for hematoma (P < 0.05).

4. Discussion

Varicocele is an abnormal dilation of the pampiniform plexus (PP) secondary to a defect in the venous renospermatic system. In very severe cases, it may be associated with subcutaneous or testicular varicose veins. Varicocele may cause subfertility or infertility and testicular pain and discomfort, i.e. a feeling of heaviness in the scrotum. In the past, most cases of varicocele were diagnosed during military service. Today military conscription is no longer mandatory in many countries, and the condition is usually diagnosed later in life or in the context of competitive sports training.

4.1. The main results were as followed

Our results showed statistically insignificant difference between patients with injection sclerotherapy and patients with laparoscopic varicocelectomy regarding age, BMI, smoking, testicular asymmetry, varicocele grade and infertility duration (P > 0.05). Also we found that statistically insignificant difference between patients with injection sclerotherapy and patients with laparoscopic varicocelectomy regarding their vital data (P > 0.05).

Our results are in consistent with Jing and colleagues who aimed to compare the efficacy of internal spermatic vein embolization of left varicocele versus laparoscopic high ligation. Their study included a total of 69 varicocele patients were admitted and given the opportunity to choose the treatment option. Among these, 26 patients were treated with sclerosing agent injection, while 43 patients underwent laparoscopic surgery. There was no significance between the studied groups regarding demographic data.

Our results showed statistically insignificant difference between patients with injection sclerotherapy and patients with laparoscopic varicocelectomy regarding their hematological, biochemical investigations and coagulation profile (P > 0.05). While our results showed statistically insignificant difference between patients with injection sclerotherapy and patients with laparoscopic varicocelectomy regarding their main semen parameters (P > 0.05).

Li and colleagues who aimed to describe a new tracking technique for using sclerosing foam with radiologic guidance. Thirty-nine men with varicocele underwent transcatheter foam sclerotherapy. Within 6 months after the procedure, all patients exhibited proven disappearance of the varicocele. At the 6-month follow-up, seminal parameters showed a significant increase in sperm concentration (37.61 \pm 23.10 vs. 50.93 \pm 36.25 \times 10⁶/ml, P < 0.05), sperm motility (65.85% \pm 5.99% vs. 71.23% \pm 7.11%, P < 0.01), progressive motility (71.76% \pm 5.34% vs. 80.06% \pm 6.14%, P < 0.05), and grade A and B motility (20.13% \pm 5.95% vs. 36.45% \pm 4.08%, P < 0.01). There have been no testes lost and no recurrent or persistent varicoceles. ¹⁰

Our results showed statistically insignificant difference between patients with injection sclerotherapy and patients with laparoscopic varicocelectomy regarding their computer-assisted sperm analysis (P > 0.05). While our findings showed higher efficiency and lower recurrence rate in patients with injection sclerotherapy than patients with laparoscopic varicocelectomy. However, this difference was statistically insignificant (P > 0.05).

Our results are in consistent with Jing and colleagues who demonstrated that there was no recurrence in patients in the sclerotherapy group during the follow-up period, however, the complication rate was 19.2%. While in laparoscopic varicocelectomy the recurrence rate of left varicocele was 4.7% and the complication rate was 44.2%. And they demonstrated that patients in the sclerotherapy group had an advantage with respect to the overall complication rate when compared with patients from the laparoscopic group (P < 0.05).

Our results showed statistically significant lower recovery time, earlier resume excursive and earlier resume sexual activity after procedure in patients with injection sclerotherapy than patients with laparoscopic varicocelectomy (P < 0.05). However, there is insignificant difference between the two groups as regard the duration of procedure (P > 0.05).

Our results supported with Mongioì and colleagues who demonstrated that after sclerotherapy a lower percentage of varicocele recurrences and a higher pregnancy rate were observed. And the hospitalization time which is significantly shorter than after surgical varicocelectomy.¹¹

Our results showed lower wound infection, Hematoma Orchitis, scrotal edema, hydrocele, scrotal emphysema and higher testicular pain in injection sclerotherapy than patients with laparoscopic varicocelectomy. However, this difference was statistically insignificant except for hematoma (P < 0.05).

Our results supported with Mongioì and colleagues who concluded that sclerotherapy should be the technique of choice for varicocele repair and it is better than surgical varicocelectomy.¹¹

Storm and colleagues who concluded that percutaneous embolization and sclerotherapy represent a

truly minimally invasive treatment with low morbidity, minimal pain and rapid recovery, since lymphatic channels are completely avoided, there appears to be no risk of hydrocele formation.¹²

Ali and colleagues demonstrated that the technical success rate of sclerotherapy was 91.8%. Follow-up revealed a clinical success rate of 83.9% and a persistence or relapse rate of 16.1%. Of the patients, 81.9% were absolutely satisfied with the outcome. In 94.9% of cases, pain or discomfort resolution was reported, and in 97% of cases, aesthetic issues were no longer a problem. Of partners, 63.2% achieved pregnancy, and in 50% of patients with preprocedural testicular atrophy, catch-up growth was observed. One patient with pampiniform plexus phlebitis received inpatient treatment with no long-term damage recorded. 13

4.2. Conclusion

In this study, we found that, patients treated with sclerosing agent injection showed higher technical success rate, lower recurrence rate, fewer complications and shorter hospitalization time, and also had a lesser financial burden compared with patients who underwent laparoscopy. Moreover, sclerotherapy does not require general anesthesia, which is another advantage of this method. Thus, we can conclude that injection sclerotherapy may be a preferable treatment option for patients with unilateral varicocele. Further studies with large scales are needed for conforming our results.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

All authors have a substantial contribution to the article.

Conflicts of interest

The authors declared that there were no conflicts of interest.

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